K001543

JAN 2 9 2001

"Abbreviated 510(k) SUMMARY"
Summary of Safety and Effectiveness

Submitter's Name & Address: Welch Allyn Inc.
4341 State Street Road
Skaneateles Falls, New York 13153

Contact Person & Telephone: Zoran I. Psenicnik
(315) 685-4400

Date Summary Prepared:

Device Name: Classification Name – Noninvasive blood pressure measurement system
Common/Usual Name – Home Blood Pressure Monitor
Proprietary Name – BPC-3000 Personal Blood Pressure Communicator

Predicate Device:

Aerotel Medical Systems (1998) Ltd., BP-Tel Trans-Telephonic Blood Pressure Measurement System, model UA-767 (ref 510(k) #K983717).

Device Description, intended Use & Effectiveness:

The BPC-3000 Personal Blood Pressure Communicator is a home-use blood pressure monitor with clinical grade accuracy and communication capability. The BPC-3000 device is indicated for non-invasive measurement of systolic pressure, diastolic pressure, and determination of hart rate in adult patients. The product is recommended for use by patients capable of understanding written and/or oral directions in home care environment. The device has the ability to collect, store, and transmit the data over the telephone line to healthcare professionals to help support effective management of patients.

The device is contraindicated for neonates, infants, or children under the age of three.

Technological Characteristics:

See attachment "III" for a comparison of the BPC-3000 to the predicate devices, submitted with the Traditional 510(k) application received by FDA on May 17, 2000. submitted with the Traditional 510(k) application received by FDA on May 17, 2000

Summary of Safety:

The system will be certified to the following general safety standards:

EN60601.1	Medical Electrical Equipment, Part 1: General requirements for Safety, Amendment 1, and Amendment 2
EN60601.1.2	Medical Electrical Equipment, Part 1: General requirements for safety 2: Electromagnetic Compatibility - Requirements and tests
EN60601.1.4	Medical Electrical Equipment, Part 1: General requirements for safety 4: Collateral Standard: Programmable electrical medical systems
EN60950	Safety of Information Technology Equipment, Including Electrical Business Equipment, Third Edition, clause 6 only.
FCC part 68	Connection of Terminal Equipment to the Telephone Network
FCC part 15	Radio Frequency Devices, Verification Level Only

Summary of Effectiveness:

The design of this device utilizes currently available technology found in many legally marketed devices. Completed design reviews and testing ensure that the BPC-3000 Personal Blood Pressure Communicator performs within the environment(s) for which it is to be marketed. The safety testing complies with the indicated standards. The software design and development (including verification and validation testing) was performed using FDA's Reviewers guidance of Medical Device Software Submissions, May 29 1998 and internal company requirements. Based on these results and the above referenced testing it is our determination that the device is safe, effective and performs within its design parameters as well as the legally marketed predicate devices. Welch Allyn Inc. will not market this device if it does not completely meet its design intent and safety functions.

PREDICATE DEVICE COMPARISON CHART		
Model	BP-Tel, UA-767	Welch Allyn, BPC-3000
Measurement method	Oscillometric	Oscillometric
Measurement Range		
Cuff Pressure	20 – 280 mmHg	0 – 300 mmHg
Systolic Range	- UNSPECIFIED -	60 – 250 mmHg
Diastolic Range	- UNSPECIFIED -	30 – 160 mmHg
Heart Rate	40 – 200 BPM	40 – 200 BPM
Measurement Accuracy		
Cuff Pressure	±3 mmHg or 2% which ever is greater	±3 mmHg
Systolic Range	Per AAMI SP10-1992	Per AAMI SP10-1992
Diastolic Range	Per AAMI SP10-1992	Per AAMI SP10-1992
Heart Rate	±5%	±5%
Residual and Resting Pressure Detection	- UNSPECIFIED -	Yes (software)
Cuff Overpressure	- UNSPECIFIED -	Yes (software)
Inflation	Automatic, micropump	Automatic, micropump
Deflation	Automatic exhaust, Constant – air release valve system	Automatic exhaust, Valve system – step deflation
Display	LCD, Digital, 16 mm character height	LCD, Digital, .780" character height
Power Source	Type AA alkaline batteries	(4) Type AA (LR6) alkaline batteries – 1.5V
Battery Life	Approx. 6 months with 6 uses per day	Approx. 6 months with 2 uses per day
Classification	Type BF	Type BF
Telephone Connection	RJ-11 type	RJ-11 type
Modem		
Dialing	Pulse/DTMF	Pulse/DTMF
Programming	DTMF	V.22 BIS
Data Transmission	DTMF	V.22 BIS
RS232	No	Yes
Environmental		
Operating Environment	+10°C -- +40 °C, <85% RH	+10 °C -- +40 °C, <90% RH (non condensing)
Storage Environment	-10C°C -- +60 °C, <95% RH	-20 °C -- +50 °C, <95% RH (non condensing)
Physical		
Dimensions	163.7(W) x 111 (D) x 66.7 (H) mm	5.67" (W) x 4.80" (D) x 2.33" (H)
Weight	330g	1.1 lbs
Safety Standards		
	UL2601	UL2601
	EN60601.1	EN60601.1
	EN60601.1.2	EN60601.1.2
	- UNSPECIFIED -	CSA 22.2, No 601
FCC/Telecom		
	UL950, clause 6 only	UL1950, clause 6 only
	EN60950, clause 6 only	EN60950, clause 6 only
	- UNSPECIFIED -	CSA 22.2, No 950
	FCC part 68	FCC part 68
	FCC part 15	FCC part 15

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 9 2001

Welch Allyn, Inc.
c/o Mr. Zoran Psenicnik
Senior Quality Engineer
Medical Division
4341 State Street Road
P.O. Box 220
Skaneateles Falls, NY 13153-4100

Re: K001543/S2
Trade Name: BPC-3000 Personal Blood Pressure Communicator, Model 52520
Regulatory Class: II (two)
Product Code: DXN
Dated: November 02, 2000
Received: November 03, 2000

Dear Mr. Psenicnik:

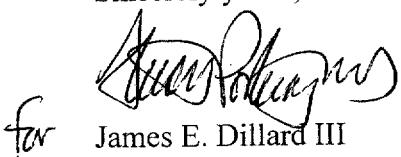
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K001543

Device Name: BPC-3000 Personal Blood Pressure Communicator

Indications For Use:

The BPC-3000 Personal Blood Pressure Communicator is indicated for non-invasive measurement of systolic pressure, diastolic pressure, and determination of heart rate in adult patients. The product is recommended for use by patients capable of understanding written and/or oral directions in home care environment. The device has the ability to collect, store, and transmit the data over the telephone line to healthcare professionals to help support effective management of patients.

The device is contraindicated for neonates, infants, or children under the age of three (3).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001543

Prescription Use ✓ AND/OR OR Over-The-Counter Use X

(Optional Format 1-2-96)

1-26-1

Division of Cardiovascular & Respiratory Devices
510(k) Number # K001543